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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,968	07/25/2001	Stanton B. Dotson	38-21(51862)B	6793

7590 11/05/2004

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EXAMINER

BAUSCH, SARAE L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/912,968	Applicant(s) DOTSON ET AL.	
	Examiner Sarae Bausch	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/23/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-39, 41--50 is/are rejected.
- 7) ☒ Claim(s) 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u> |

DETAILED ACTION

The examiner reviewing your application at the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Sarae Bausch.

1. Currently, claims 35-50 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are either newly presented, as necessitated by amendment, or are reiterated from the previous office action.

Response to arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections and Objections

3. The rejection to claims 35-49, under 35 U.S.C. 112, 2nd paragraph, made at section 13 and 14, page 5-6 of the previous office action, is withdrawn in view of the arguments made at section III, page 14-16 of the response mailed 8/23/2004. The arguments were found persuasive and the rejection has been withdrawn.

4. The rejection to claims 40, 43, and 44, under 35 U.S.C. 112, 2nd paragraph, made at section 15, page 6 of the previous office action, is withdrawn in view of the amendment to the claims.

5. The rejection to claim 47, under 35 U.S.C. 112, 2nd paragraph, made at section 16, page 7 of the previous office action, is withdrawn in view of the amendment to the claims.

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6. The rejection of claims 35, 36, 40-42, and 44-46, under 35 U.S.C. 102(a), is withdrawn in view of arguments made in section 4, page 17-18 of the response mailed 8/23/2004. The arguments were found persuasive and the rejection has been withdrawn.
7. The rejection to claim 47, under 35 U.S.C. 102(a), is withdrawn in view of the amendment to the claims.
8. The rejection to claim 40, under 35 U.S.C. 103, made in section 21, page 10-12 of the previous office action, is withdrawn in view of the arguments made at made in section V, page 20 –25 of the response mailed 8/23/2004. The arguments were found persuasive and the rejection has been withdrawn.
9. The objections made to the specification regarding an embedded hyperlink is withdrawn in view of the amendment to the specification.
10. The objections made to the specification in Example 1 is withdrawn in view of the amendment to the specification.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

11. Claim 50 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, necessitated by amendment. The claim contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation of “hybridizes under stringent hybridization conditions” allows for

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polynucleotides with substantial variation with regard to 3' end of the *Pisum sativum* rbcS E9 gene. While the specification teaches examples of appropriate stringency hybridization conditions (page 13, lines 9-13), these examples do not connote structural limitation to the claims and as such it is not clear what resulting structure will occur from hybridization. Even stringent hybridization would tolerate mismatches and result in sequences that correspond to mutants, variants, and homologs of the 3' end of the *Pisum sativum* rbcS E9 gene which is not disclosed in the specification. The claim language encompasses sequences that correspond to mutated fragments, allelic variants, splice variants, genomic sequence, sequences from other species and so forth and thus the claim encompasses sequences not described by the specification.

The instant claim is drawn to undisclosed sequences encoding modification that have not been contemplated. The specification provides insufficient written description to support the genus encompassed by the claim. Absent a written description, the specification fails to show that the applicant was "in possession of the claimed invention" at the time the application for the patent was filed. Further, the genus of polynucleotides comprised by the claim is a large variable genus, which can potentially encode proteins of diverse functions and read on genomic sequences. The specification only discloses a selected number of species of the genus; i.e. SEQ ID NO 2 (SEQ ID 7-9 and 28, which are part of SEQ ID NO 2), which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the genus. Thus one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed with respect to claim 50.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was

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in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of SEQ ID NOS: 2, 7-9, and 28 the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993), and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

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Accordingly, the specification does not provide a written description of the invention of claim 50.

Maintained Rejections

Claim Rejections - 35 USC § 112

Written Description

12. The rejection of claim 50 under 35 U.S.C. 112, in the previous office action, is maintained and incorporated herein (see page 2-4 of previous office action mailed 3/22/2004).

Response to Arguments

The response traverses the rejection, on page 11-12, that because the claimed nucleic acid sequence may include sequences from other species, mutated fragment sequence, allelic variants and so forth does not require that Applicants describe each and every one of these molecules. This argument has been thoroughly reviewed but was not found persuasive because although the specification does not need to describe each and every one of the species within the broad genus, the specification does need to disclose a representative number of the species. Although the specification does describe SEQ ID NO 2 it does not describe a representative number of mutants, homologs, and variants of the 3' end of the *Pisum sativum* rbcS E9 gene which is encompassed by the scope of the claims. The response asserts that the specification describes gene sequences, corresponding sequences preferred sequences, and so forth of *Pisum sativum* rbcS E9 gene (specification page 26, line 1 through page 28 line 14). This section of the specification does not describe genomic sequences, mutants, variants, and homologs of the 3' end of the *Pisum sativum* rbcS E9 gene, which is encompassed by the scope of the claim. The claim provides for a large genus of nucleic acids that includes undisclosed genes, partial genomic

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sequences, mutants, variants and homologs of SEQ ID NO 2, however the disclosed structural feature of SEQ ID NO 2 does not provide for a substantial portion of the claimed genus.

The response traverses that a person of ordinary skill in the art, after reading the specification, would understand that the Applicant had possession of the claimed invention. These arguments have been thoroughly reviewed but were not found persuasive because the specification only describes a nucleic acid of SEQ ID NO 2 (SEQ ID NO 7-9 and 28 are of SEQ ID NO 2) and does not reflect possession of sequences from other species, mutated fragment sequence, allelic variants, splice variants, genomic sequences and so forth of any sequence of a 3' end of the *Pisum sativum* rbcS E9 gene. The claim encompasses a large variable genus and beyond providing the sequence data for SEQ ID NO 2, the specification does not provide teaching or guidance to obtain any specific homolog, mutant, or variant of the 3' end of the *Pisum sativum* rbcS E9 gene. Therefore, one of ordinary skill in the art would not be unable to determine whether or not a DNA molecule would fall into the broad genus of the claimed invention.

While applicants amendments and arguments have been considered, the new recitation of "under stringent hybridization conditions" does not obviate the presently maintained written description (see section 5 in the instant office action).

Claim Rejections - 35 USC § 102

13. The rejections of claims 35, 41, 47, and 49 under 35 U.S.C. 102(b) as being anticipated over Hamilton et al (*Gene*, 1997) in the previous office action, is maintained and incorporated herein (see page 8-9 of previous office action mailed 3/22/2004).

Response to Arguments

The response traverses that Hamilton et al. does not include all the limitations of the present claims. Specifically, the response asserts that Hamilton et al. does not disclose “a method to detect the expression of a first nucleic acid molecule in sample employing hybridizing a complementary DNA of an mRNA from a second transgenic nucleic acid molecule with at least one oligonucleotide designed to hybridize to the second transgenic nucleic acid molecule where the hybridization indicates the expression of the first transgenic nucleic acid molecule in a sample”. This traversal has been thoroughly reviewed but was not found persuasive because Hamilton et al. does teach a method to detect the expression of a first nucleic acid molecule in a sample employing a complementary DNA of an mRNA from a second transgenic nucleic acid molecule with at least one oligonucleotide designed to hybridize to the second transgenic nucleic acid molecule where hybridization indicates the expression of the first transgenic nucleic acid molecule.

Hamilton demonstrates the expression of transgenes in a BIBAC vector (p. 113, 1st column, 3rd paragraph), wherein a successful transfection into the host plant is determined based upon the following transgenic nucleic acids: *sacB* gene, GUS-NPTII gene (beta-glucuronidase – neomycin phosphotransferase II), and the HYP gene (hygromycin phosphotransferase). In one example, the first transgenic nucleic acid is the *sacB* gene and the second transgenic acid is the GUS-NPTII and/or HYG gene:

Potential transgenic plants were initially tested by PCR using primers to the GUS-NPTII and HYG [...].

[...] Plants that tested positive for the BIBAC T-DNA by PCR [*thereby amplification, claim 35 step ii, and*

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claim 41] were all verified by Southern analysis [*thereby hybridization, claim 35 step iii, and claim 49*] using a NPTII specific probe. (p. 113, 1st column, 3rd paragraph)(see also figure 3).

A second example of the method demonstrated is wherein the first transgenic nucleic acid corresponds to large DNA inserts into the BIBAC1 and BIBAC2 plasmids. The second transgenic nucleic acid corresponds to the GUS-NPTII. Hamilton demonstrates in “[f]igure 4b and c shows the hybridization of BIBAC DNA to a GUS-NPTII-specific probe and a HYG-specific probe, respectively” (p. 113, 2nd column, 2nd paragraph). At page 113, 1st column, Hamilton et al. teaches amplifying the second transgenic nucleic acid (primers to Gus-NPTII) and using a probe to NPTII (again to second transgenic nucleic acid). It is noted that claim 35 does not require that the step of “providing a complementary DNA of the mRNA” be limited to the reverse transcription step of RT-PCR due to the dependency of claim 41. Claim 41 states the “amplifying” step, step ii of claim 35, be either PCR or RT-PCR. Accordingly, claim 35 has been broadly interpreted to encompass any means of “providing a complementary DNA of the mRNA” which includes providing genomic DNA as DNA is “inherently complementary” to mRNA. The southern analysis step of Hamilton inherently teaches hybridizing said complementary DNA with at least one probe designed to hybridize to said second transgenic nucleic acid. Hamilton et al. anticipates claims 35, 41, 47, and 49 and the rejection is maintained.

Claim Rejections - 35 USC § 103

14. The rejections of claims 35-39, 41-50 under 35 U.S.C. 103(a) as being unpatentable over Hunt (*DNA*, 1998) in view of Freeman et al. (*Biotechniques*, 1999) in the previous office action,

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is maintained and incorporated herein (see page 9-12 of previous office action mailed 3/22/2004).

Response to Arguments

The response traverses on page 22-23 of the response mailed 8/23/2004 that the cited references does not render the present independent claims obvious, since the claims are not taught nor suggested by the cited references. The response asserts that the cited references do not disclose or suggest a method to detect expression of a first transgenic nucleic acid molecule in a sample comprising amplifying a complementary DNA from an mRNA from a second transgenic molecule and hybridizing the cDNA with at least one oligonucleotide designed to hybridize to the second transgenic nucleic acid molecule where hybridizing indicates the expression of the first transgenic nucleic acid molecule in a sample. This traversal has been thoroughly viewed but was not found persuasive because Hunt does teach a method of detecting a 1st transgenic nucleic acid (pAH10) by amplifying a complementary DNA (page 331, 2nd full paragraph, pAH10:E9 labeled with Klenow in the presence of [α -³²P]dATP) from mRNA (p. 331, 1st full paragraph, total cellular RNA was isolated) from a second transgenic nucleic acid molecule (page 331, 2nd full paragraph, fragment carries entire rbcS region) and hybridizing the cDNA with at least one oligonucleotides designed to hybridize to the second transgenic nucleic acid molecule (page 331, 2nd full paragraph, renatured probe from RNA-protected sequence covering entire rbcS region (2nd transgenic nucleic acid), RNA and probes were hybridized using hybridization buffer)) where hybridizing indicates the expression of the first transgenic nucleic acid molecule in a sample (page 331, 2nd full paragraph, S₁ digest and analysis of protected fragments).

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The response further traverses on page 23 of the response mailed 8/23/2004, that Hunt et al. does not disclose or suggest a method for detecting expression of a first transgenic nucleic acid molecule. The response asserts that Hunt does provide an identification and characterization of cryptic polyadenylation sites in the 3' region of a pea rbcS-E9 gene and as such, asserts that the Examiner's conclusion of obviousness is based on improper reasoning and a misinterpretation of the art. This traversal has been thoroughly viewed but was not found persuasive because Hunt does teach a method of identifying the 3' end of pea rbcS-E9. Hunt does teach that the 3' region of the pea rbcS-E9 gene does contain a number of discrete, cryptic polyadenylation sites, but in order to determine that the 3' end of the pea rbcS-E9 gene does contain these sites, the 3' end of pea rbcS-E9 must be identified and detected and therefore Hunt et al. teach a method of detecting the expression of a first transgenic nucleic acid molecule by detecting the 3' end of the rbcS-E9 gene.

In response to applicant's argument on page 24 of the response mailed 8/23/2004, that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Further, Hunt in view of Freeman does teach a method to detect expression of a first transgenic nucleic acid molecule in a sample comprising amplifying a complementary DNA from an mRNA from a second transgenic molecule and hybridizing the cDNA with at least one oligonucleotide designed to hybridize to

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the second transgenic nucleic acid molecule where hybridizing indicates the expression of the first transgenic nucleic acid molecule in a sample, see response above (1st paragraph, response to arguments, section 13, instant office action). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to improve the detection method of Hunt and further modify the mRNA expression analysis to utilize quantitative RT-PCR which includes amplification along with primers and probes designed for quantitative RT-PCR as per the teachings of Freeman et al. because Freeman teaches that quantitative RT-PCR provides increased sensitivity in mRNA detection.

In response to applicant's argument on page 23 of the response mailed 8/23/2004 that Hunt is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Hunt et al. is analogous art as it employs nucleic acid detection of transgenic expression. Further, Hunt et al. disclose a method for detecting the expression of a first transgenic nucleic acid molecule in a sample by hybridizing a complementary DNA of mRNA transcribed from a second transgenic nucleic acid molecule with at least one oligonucleotide designed to hybridize to the second transgenic nucleic acid molecule (see section 13, 1st paragraph Response to Arguments, instant office action). Further, Hunt disclose detecting the gene *rbcS-E9* gene which is the second transgenic nucleic acid molecule of the instant claims and therefore Hunt et al. is analogous art. With regard to the argument that Hunt is not pertinent to the particular problem that the present inventors faced, it is noted that the claims are broadly drawn to detecting any

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first transgenic nucleic acid by detecting any second transgenic nucleic acid. The fact that Hunt et al. in view of Freeman et al. disclose detection of specific nucleic acids does not exclude the reference as art. The claims do not specifically set forth any particular embodiments to distinguish from the teaching of Hunt and Freeman et al.

The response asserts that Freeman et al. does not make up what Hunt lacks and further asserts that Freeman et al. does not disclose a method for detecting the expression of a first transgenic nucleic acid molecule in a sample by hybridizing a complementary DNA of mRNA transcribed from a second transgenic nucleic acid molecule with at least one oligonucleotide designed to hybridize to the second transgenic nucleic acid molecule where the hybridization indicates the expression of the first transgenic nucleic acid molecule in the sample. This traversal has been thoroughly reviewed but was not found persuasive because the reference of Freeman et al. teaches the benefits of RT-PCR to quantify mRNA. Hunt in view of Freeman et al. meets the limitations of the method for detecting the expression of a first transgenic nucleic acid molecule and Hunt in view of Freeman et al. teaches the use of RT-PCR to meet the limitations of claims 36, 41, 42, 47, 48, and 50.

Conclusion

No claims are allowable.

Claim 40 has been found to be free of the cited prior art, but is objected to for being dependent on a rejected claim.

Claim 39, would be free of the cited prior art if amended to recite: A method according to claim 35, wherein said second transgenic nucleic acid molecule is the nucleic acid of SEQ ID No 2.

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15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

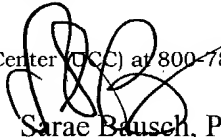
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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JEHANNE SITTON
PRIMARY EXAMINER

11/4/2004


Sarac Bausch, PhD.
Examiner
Art Unit 1634